Alliance Public Study Result Summary
Alliance A091102

What this study is about

A study that looked at how well a drug worked in treating patients with sarcoma that had spread to other places in the body and usually could not be cured or controlled with treatment or had spread to other places in the body.

The full title of this study is: Phase II study of MLN8237 in advanced/metastatic sarcoma

Why the study was done

A protein called Aurora kinase A (AURKA) is present on many sarcomas. A drug called MLN8237 (common brand name alisertib) can block the function of this protein. Studies in the lab have shown that MLN8237 can lead to reduction in the growth of sarcomas by blocking AURKA.

This study was done to see if MLN8237 can help slow the growth of sarcomas in people.

Study results

These results are for people with metastatic sarcoma. A total of 72 patients were enrolled on the study.

The study found that two people with angiosarcoma had some tumor shrinkage. Most of the other people enrolled did not experience shrinkage of the tumor. It was that on average, people did not have growth in the tumor for about 3 months. Some people had tumor growth sooner than 3 months, and some people had tumor stabilization for longer than 3 months.

The most common serious side effects included: lowering of the white blood cells, anemia and lowering of the platelet count.

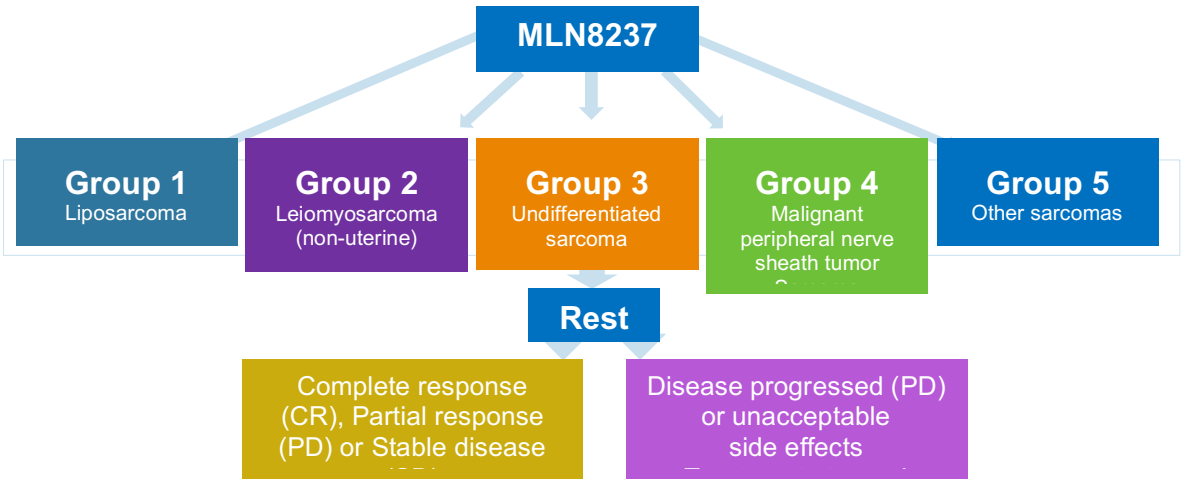
What the results mean

This means that MLN8237 has limited activity in patients with sarcoma and the medication is no longer being studied in this disease at this time because not enough people were found to have shrinkage from the medication.

How the study worked

Patients were placed in five groups by the type of sarcoma that they had. All patients got MLN8237.

Here's a picture that explains how patients were placed into this study.



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When did the study start and end? The study started in August 2012. All patients were enrolled by December 2013.

How many patients joined? 72 patients enrolled in this study and included patients with leiomyosarcoma, liposarcoma, undifferentiated sarcoma, and malignant peripheral nerve sheath tumor. There were also a number of other patients with less common sarcoma subtypes, including angiosarcoma.

Talk to your doctor if you want more information about this study.

Scientific publications about this study

This summary includes information in the following article:

- **Phase II Study of MLN8237 (Alisertib) in Advanced/Metastatic Sarcoma.** Dickson MA, Mahoney MR, Tap WD, D'Angelo SP, Keohan ML, Van Tine BA, Agulnik M, Horvath LE, Nair JS, Schwartz GK. Ann Oncol. 2016 Oct;27(10):1855-60. doi: 10.1093/annonc/mdw281. Epub 2016 Aug 8.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT01653028

This study was sponsored by the Alliance for Clinical Trials in Oncology – a national clinical trial network group that runs large cancer clinical trials. The Alliance is supported by the National Cancer Institute (NCI) and brings researchers together to develop better treatments for cancers. More information about the Alliance is at http://www.allianceforclinicaltrialsinoncology.org.

This summary lists what is known about this research study as of October 2016.
New Information may be available.

We thank the people who joined this study and made it possible.
We do research to try to learn the best ways to help patients.
The people who joined this study helped us to do that.

Thank you for your interest in learning more about cancer research advances.